DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 1 2000

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Francis C. Lynch, Esquire
Palmer & Dodge, LLP
One Beacon Street
Boston, MA 02108-3190

Re: Docket No. 99P-3083/CP1

Dear Mr. Lynch:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted on August 12, 1999. Your petition requests that the Agency refuse to accept for filing any abbreviated new drug application for gabapentin tablets in which Neurontin tablets are used as the reference listed drug product.

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

99P-3083

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